Report of Dr. Steven M. Hertz Regarding Medical Monitoring of Bard Retrievable IVC Filters

EXPERT QUALIFICATIONS

1. I currently serve as Clinical Chief, Department of Surgery, and Chief, Vascular Surgery Section at Saint Barnabas Medical Center, located in Livingston, New Jersey. My medical degree was conferred by The Albert Einstein College of Medicine, located in Bronx, New York and I subsequently completed a residency in general surgery at Mount Sinai Medical Center in New York City. I went on for further vascular surgery specialty fellowship training at the Hospital of the University of Pennsylvania in Philadelphia, Pennsylvania and received board certification in general surgery with special certification in vascular surgery. I remain currently specialty certified. In addition to my clinical work, I am involved with the teaching of medical students, residents and vascular trainees; I serve as the site director of our Vascular Surgery Fellowship Program. I have professional and scholarly experience with inferior vena cava (IVC) filters in general and Bard IVC filters in particular as a result of my training, my clinical practice, and through information gained at professional conferences, discussions with colleagues, and my review of the medical literature. The opinions in this Declaration are expressed to a reasonable degree of medical certainty.

OVERVIEW

2. I have been asked to address whether medical monitoring of patients who have a retrievable Bard IVC filter implanted in their bodies after it was inserted is medically appropriate and necessary to assure the accurate diagnosis of filter-related complications, and prevention and/or mitigation of adverse events. If monitoring is indicated, I also have been requested to specifically recommend the type of monitoring that is needed. In addressing these questions, I have relied on my education and training, my clinical experience, available medical literature and additional documents provided to me. As explained herein, the risk of serious harm, including life-threatening complications associated with the fracture, tilt, migration and other complications of these retrievable Bard IVC filters that are not removed is well-documented in the medical literature.[Tam (2012), Deso (2016), Kalva (2006), Nicholson (2010)] This risk becomes more severe with increasing time after implantation.[Hull (2009), Angel (2011)] The condition of these retrievable Bard IVC filters is presently unknown in the vast majority of patients and is not being monitored as part of patients' current medical care. A prudent, necessary and reasonable medical monitoring protocol can and should be implemented and this group of patients is recommended to receive medical monitoring: 1) to identify the patients who remain at increased risk for filter-related complications, 2) to provide for the accurate diagnosis of filter-related complications, and 3) to assist in prevention and/or mitigation of progression to more serious or life-threatening complications.

METHODOLOGY

3. In order to respond to these questions, I have relied on my training and experience and used the following methodology. First I determined whether the defined population of patients who have a retrievable Bard IVC filter implanted in their bodies for more than 90 days was at an increased risk for certain filter-related complications, specifically penetration through the IVC wall, positional change or migration from the original implant site, and fracture with or without distant embolization of the filter or filter fragments. This information included assessments of whether the risk increases over time and information on the mechanism of harm if adverse events occurred. In order to do this, I performed a thorough review of the available peer-reviewed published medical literature, as well as the reports of relevant medical societies, and relevant governmental health authorities to determine both the available epidemiological and statistical data on increased risk of these complications. To accomplish a comprehensive literature review, I performed multiple searches at multiple times utilizing different reference search databases including PubMed, Ovid Medline and Google Scholar, and using a variety of search phrases such as IVC filter, complications and retrievable. I pursued information on references cited within pertinent articles that I found on these topics. I then assessed the reliability of these sources and authorities, as well as the statistical power and strength to support their conclusions. I was additionally provided with information from specific expert analysis and reports and from Bard company documents. I also relied on my clinical experience and the information I have obtained from attending professional conferences and from direct discussions with my colleagues in the clinical practice of vascular surgery and interventional radiology. A list of specific references reviewed and relied on in writing the report appears at the end of this report.

4. In reviewing this information, I investigated whether the experts publishing on these issues identified elevated risk of harm to patients based on reliable methods, and whether they were recognizing the need for some form of medical monitoring of this population to respond to an increased risk, and whether they identified the benefits of such monitoring. I then relied on my experience and the available literature to determine if there was a well-accepted, reliable, noninvasive diagnostic test available to monitor this population to identify the existence of IVC filter-related complications with the likely potential to lead to prevention and mitigation of more severe complications, including organ damage and death.

5. In reviewing the available diagnostic imaging procedures that are available and could provide this diagnostic information, I considered the specificity of the imaging, the possibility of false positives and false negatives, the invasiveness of the procedure and the risks and benefits of the procedure, and evaluated all this information in light of the anticipated benefits of the monitoring that I am recommending for this population of at risk IVC filter patients. In other words, I evaluated whether the benefits of the monitoring would substantially outweigh the risks of such monitoring. I then relied on my experience and the available literature to determine if the recommended monitoring procedures were in fact presently being carried out in the typical practice of clinical care and follow up of IVC filter patients, and then considered how the patients and their treating doctors could

use and benefit from obtaining the diagnostic information that they would obtain as a result of the monitoring.

6. As a result of carrying out the methodological steps noted above, it is my opinion based on the totality of the evidence and my clinical experience, to a reasonable degree of medical certainty that medical monitoring, as defined below, is prudent, reasonable and necessary for patient safety. My opinions regarding medical monitoring pertain to the Bard Recovery, G2, Eclipse, and Meridian filters; however, I reserve the opportunity to supplement this report to address the later generation filters (e.g., Denali) based on review of additional data, to address other matters of relevance, or to address opinions of defense experts.

7. My curriculum vitae and a listing of my professional testimony in the past 4 years is attached as Exhibits A and B. My billing rate is $500 per hour.

BACKGROUND

8. The mainstay of therapy for deep venous thrombosis (DVT) involves treatment with blood thinners (anticoagulant medications). When significant contraindications to or failures of anticoagulation arise, alternative therapies including inferior vena cava (IVC) filters are considered.

INFERIOR VENA CAVA FILTERS INTRODUCED

9. Intravascular filter devices are metallic-based "straining" filters placed under radiological guidance into the main vein returning towards the heart and lungs from the lower extremities and pelvis, the IVC. If a clot breaks away from its primary location and travels towards the lungs, these filters are designed to capture the traveling clot and prevent a major pulmonary embolism. A variety of filter designs have been utilized since their introduction; filter materials and delivery mechanisms have changed and evolved. The initial IVC filters were conceived of and designed as permanent implants. These permanent implants underwent bench top and animal studies which investigated filter component choice, configuration, optimal dimensions, and component fatigue. Greenfield (1990), Proctor (2000)

RETRIEVABLE FILTERS

10. Retrievable filter designs were developed largely to address concerns related to the long-term presence of a metallic foreign body, especially in younger patients and in patients in whom the filter was placed for a preventative ("prophylactic") indication. The United States has witnessed a dramatic increase in filter usage, and more than 250,000 filters were estimated to be placed in 2012, many of those filters with retrievable designs. Smouse (2010), Kuy (2014)

BARD RETRIEVABLE FILTERS

11. FDA clearance for the retrievable Bard Recovery Filter was obtained in November 2002. In the FDA 510(k) application, substantial equivalence is cited to two predicate devices: the Bard Simon Nitinol/ Straightline System (SNF) and the Titanium Greenfield Filter (GF). The Bard Recovery filter was sold beginning in early 2003. The Bard G2 filter was introduced in 2005 and was predicated on the Recovery Filter. Modifications of the G2 design, the G2x and G2 Express were introduced in 2008. For the purpose of this document, I will use the term G2 filter to refer to the group of filters which include the G2, G2x and G2 Express. The Bard Eclipse IVC filter introduced in early 2010 and was predicated on the G2 Express. The Bard Meridian filter was released in August 2011 and was predicated on the Eclipse Filter.

RETRIEVABLE FILTERS: COMPLICATIONS/SAFETY CONCERNS

12. Cumulative reports of life-threatening and fatal complications of retrievable filters led to an August 2010 FDA alert warning United States clinicians of the risks associated with retrievable filters including filter migration, IVC perforation, filter component fracture, and filter/filter component embolization.[FDA (2010)] In a systematic review of data from available clinical trials and the FDA MAUDE [Manufacturer and User Device Experience] database inclusive of nearly 7000 patients, Angel (2011) found, "The numbers of unanticipated complications were highest for perforation, migration, and fracture of the filters; these events were reported more frequently with prolonged use of the filter (>30 days)." [Angel (2011)] Nicholson (2010) found that , "The Bard Recovery and Bard G2 filters had high prevalences of fracture and embolization, with potentially life-threatening sequelae." [Nicholson (2010)] "Further implantation of these particular devices has been halted at our institution." [Nicholson (2010)] Multiple published reports have highlighted the increased risks associated specifically with the Bard Recovery and G2 retrievable IVC filters. [Tam (2012), Deso (2016), Kalva (2006), Nicholson (2010), Hull (2009), Angel (2011)] The Angel study reveals that Bard's G2 filter accounted for 83.5% (157/188) of all filter fracture adverse event reports in the MAUDE database from January 1, 2000 through December 31, 2010. [Angel (2011)]

13. A second systematic review of the MAUDE database covering a later time period, January 1, 2009-December 31, 2012, reported similar results showing that 76.3 % (1,063/1,394) of retrievable filter adverse events in the database were associated with Bard filters—approximately 3-fold higher than the number of adverse events reported for all five other retrievable filters combined. These authors also found that 86.8% (1,394) of the filter-related adverse events were associated with retrievable filters, while 13.2% (212) were associated with permanent filters. [Andreoli (2014)]

COMPLICATIONS: FILTER PERFORATION/PENETRATION

14. Components of an IVC filter, often the tips of the arms and legs, may protrude completely through the wall of the IVC. The terms perforation and penetration both connote full vessel wall violation; penetration is used by some authors to denote involvement of adjacent structures or organs. A definition is offered in the 2016 revised American College of Radiology (ACR) Practice Parameters: "Filter penetration – penetration of the vein wall by a filter strut with transmural incorporation. For quality improvement reporting purposes, the definition of IVC penetration by a filter is filter strut or anchor devices extending >3 mm outside the wall of the IVC as demonstrated by CT, venography, or autopsy." ACR-SIR (2016) The risk of IVC perforation after long-term implantation from the Bard Recovery and G2 filters has been reported at rates as high as 100% and 86% respectively. Hull (2009), Purcell (2014) Observations demonstrate that the risk of perforation rises with time after implantation. Hull (2009) Perforations were associated with adverse consequences, as published reports substantiate that perforation and fatigue predispose to filter component fracture… "In the present study, all fractures occurred in arms that had previously shown perforation of the IVC. …Scanning electron microscopy of the fractured arm surfaces demonstrated changes characteristic of bending fatigue fractures. …" Hull (2009) "The current study is in agreement with the findings of Kalva et al…that arm perforation and structural weakness leads to fracture." Hull (2009) In addition to creating stresses on the filter limbs which may predispose to fracture, perforation/penetration can directly injure adjacent structures and organs. In a MAUDE database review, Northwestern University Interventional Radiologists note, "multiple cases of IVC penetration were associated with duodenal or small bowel penetration, penetration into adjacent retroperitoneal structures such as the vertebral bodies and disks, or retroperitoneal bleeds. Even if the overall incidence of these complications is relatively low, the clinical consequences can be significant, particularly for a device placed for prophylactic indications." Andreoli (2014)

COMPLICATIONS: FILTER POSITIONAL CHANGES AND MIGRATION

15. An IVC filter has the potential to change position from the original site of implantation either by tilting, deforming, migrating or embolizing into a new location. According to the ACR-SIR (2016) definition, "Filter movement [is] a change in filter position compared to its deployed position (either cranial or caudal) of >2 cm as documented by plain-film imaging, CT, or venography." ACR-SIR (2016) Migration is movement to an adjacent rather than distant area. Migration from the original implant site to a distance of more than 2 cm has been documented at rates exceeding 20% in Recovery and G2 filters. Hull (2009), Nicholson (2010) [redacted] Cantwell (2009) noted investigators found significantly more caudal migrations for the G2 as compared to the Recovery." Cantwell (2009) [redacted] Angel (2011) found that migration in G2 filters exceeded that of other filter types and constituted 25% of adverse event reports to the MAUDE database. Angel (2011)

COMPLICATIONS: FILTER FRACTURE AND EMBOLIZATION

16. The 2010 FDA Alert noted a concerning rate of filter fracture and embolization related to retrievable filters. FDA (2010) ACR-SIR (2016) definitions, "Filter fracture – any loss of a filter's structural integrity (i.e., breakage or separation) documented by imaging or autopsy." "Filter embolization – postdeployment movement of the filter or its components to a distant anatomic site completely out of the target zone." ACR-SIR (2016) A 2009 IVC Research Panel discussed the problem of unexplained filter fractures: "In reality, the IVC is complex and poorly understood. Flow in the IVC varies dramatically with volume status, cardiac output, and patient position. The size and cross-sectional shape of the IVC change constantly, partially as a result of these factors. The IVC is also subject to external axial compression by the peritoneal contents, longitudinal compression by the movement of the diaphragm, and likely by additional yet unappreciated external forces. Kaufman (2009)

17. A study from the Stanford Department of Interventional Radiology performed a comparison among filter types and stated, "Early conical Bard Peripheral Vascular (Tempe, AZ) filters were associated with the highest reported rates of fracture. The fracture rate for the original Bard Recovery device was 5.5 to 25% with an estimated incidence of 39.5% at 65.7 months." Deso (2016) Cleveland Clinic investigators reported an estimated Recovery fracture rate of 40% at 5.5 years. Tam (2012) In a later publication, the Cleveland Clinic group showed the fracture rate for the Bard G2 devices is estimated at 38% at 60 months after implantation. An (2014) The Bard G2 filter constituted 31% of the fractures reported to the MAUDE database. Angel (2011) Nicholson evaluated the condition of implanted IVC filters and concluded that "(t)he Bard Recovery and Bard G2 filters have a high prevalence of fracture and embolization, with life-threatening sequelae." Nicholson (2010) In an Invited Commentary, Johnson stated: "Although fracture is not a complication exclusive to Bard filters, review of the literature suggests that they fracture at a much higher rate than do other filters." Johnson (2012) Multiple studies have shown that the Recovery and G2 fracture rate increases with time from implantation. Deso (2016), An(2014), Vijay (2012) This time-dependent increase in fracture rate is demonstrated in the following table from a 2014 article from the Cleveland Clinic An (2014):

Table 4 Estimate of G2 Filter Fracture Prevalence Over Time

Time Point after Filter Placement	Patients without Known Fracture (n)	Patients with Known Fracture (n)	Fracture Prevalence	
			Estimate (%)	95% CI (%)
3 mo	337	0	0	0.000, 0.009
6 mo	225	1	0.44	0.000, 0.027
1 y	156	1	0.63	0.000, 0.039
2 y	102	6	5.6	0.023, 0.118
3 y	75	9	10.7	0.055, 0.193
4 y	42	11	20.8	0.118, 0.336
5 y	20	12	37.5	0.229, 0.548

CI = confidence interval.

18. The Canadian Government's Section Health Canada's 2016 alert included the Bard G2 filter in its data collection and documents 121 overall proven incidents of serious complications, including filter fracture and fragment embolization, intracardiac migration, cardiac perforation, cardiac tamponade, and death. Health Canada Alert (2016)

Dislodgement of the retrievable IVC filter in its entirety or component fragments (embolization) has been observed at significant rates in both Bard Recovery and Bard G2 Filters. The 2010 FDA alert was published in response to an increasing number of reported complications in the MAUDE database and many of these complications included fractures and embolizations associated with the Bard Recovery and G2 filters.[FDA (2010)]

19. Multiple studies citing high fracture and embolization rates among these Bard filters have been reported in the medical literature , and some reported cases reflecting the severity of the complications including death.[Tam (2012),Deso (2016),Nicholson (2010) ,An (2014)] Nicholson (2010) reports, "At least 1 strut in 7 of the 28 Bard Recovery filters fractured and embolized (25%). In 5 of these 7 cases, patients had at least 1 fragment embolize to the heart (71%). Three patients experienced life-threatening symptoms of ventricular tachycardia and/or tamponade, including 1 patient who experienced sudden death at home." [Nicholson (2010)] A case report describes emergency removal of a Bard G2 filter which embolized intact to the heart causing shock and life-threatening arhythmias.[Kuo (2007)] In a video personally describing her experience as a patient, Emory nurse Mary Duffie details her collapse and need for emergency heart surgery from a laceration in her heart created by a fractured Bard IVC filter fragment. [Duffie Video] A recent published case reported that a patient coughed up a 5cm long fragment of a G2 filter 8 years after its insertion.[Mehanni (2016)] [redacted] An Australian study notes a fatal complication from filter embolization.[DeVilliers(2008)] While the experience of practitioners and medical centers may result in these types of individual case reports, or series of case reports, demonstrating that serious adverse events are not isolated,[Kuo (2007), Mehanni (2016), Desjardins (2010), Vossen (2012), Pierichetti (2016), Saeed (2006), Vergara (2007)] underreporting or lack of recognition of the cause of these clinical events would result in an underestimate of the true incidence.

COMPLICATIONS: RISK IS CUMULATIVE AND TIME-RELATED

20. Angel (2011) states, "The MAUDE database contained 192 reports of filter migration and embolization. Of these incidents, 10% occurred during the first 30 days after placement, whereas 90% occurred >30 days after placement."[Angel (2011)] Multiple reports show a substantial increase in the rate of Bard Recovery and G2 filter complications as the time period from implantation increases.[Deso (2016), Hull (2009), An (2014), An(2014) ,Vijay (2012)] This increase in complications as a function of implantation time is supported by electron microscopy findings from a study examining the mechanism of fracture in failed filters which concludes that 87% of the tested fractured components demonstrated high-cycle metal fatigue secondary to accumulated damage from chronic, repetitive in vivo motions.[Kuo (2012)] Kuo concludes, "The risk of filter fracture increases after 408 days (i.e., 1 year) of implantation and is associated with symptomatic extravascular penetration and/or intravascular embolization."[Kuo (2012)] A 2016 publication from Interventional Radiologists

at Stanford University states, "...[T]he true risk of complications from these filter types could be even higher than currently reported, as complications increase after long dwell times."[Deso (2016)]

"ASYMPTOMATIC" COMPLICATIONS

21. There is an inherent misnaming in labeling certain complications of failing IVC filters as "asymptomatic." While many of the complications related to retrievable IVC filters identified *appear* asymptomatic at the initial time of diagnosis of a filter complication, there is strong evidence to suggest that these asymptomatic complications raise significant safety concerns and predispose to later significant clinical problems. Much of this evidence has been cited earlier in this document but can be summarized as follows: Perforation is present in a large number of Bard Recovery and G2 filters after long-term implantation.[Hull (2009), Purcell (2014)] IVC perforation/penetration can lead to serious consequences even though they may not be preceded by patient symptoms.[Andreoli (2014)] Material thinning and structural changes of the legs and arms were made to the Recovery and G2 filter design to allow for retrievability. Investigators cite that IVC wall perforations in these retrievable designs create material stress and asymmetry and predispose to structural weakness of the filter components.[Kalva (2006), Hull (2009)] Dr. Murray Asch, a Canadian interventional radiologist who performed some of the sentinel clinical studies on the Bard Recovery filter, stated his concern about the potential dangers of an asymptomatic fracture and also highlighted the benefits of monitoring in his May 2, 2016 deposition at pages 36-37:

> Q. And what happened with patient 33?
> A. As a result of the close monitoring of these patients, we were able to identify the fractures and we were able, fortunately, to safely retrieve the filter before a more serious adverse event could have occurred.
> Q. The piece that broke off, it's a piece of metal that separated from the filter?
> A. That's correct.
> Q. And about how long was that piece of metal?
> A. About one inch.
> Q. And is a one-inch piece of metal in your vena cava something that would concern you as far as the patient's safety?
> A. Yes, because that piece of metal could have then migrated either to the heart or lungs where it could have been lethal.

Asch's concerns are not theoretical; filter components and even entire filters have been demonstrated to migrate and embolize from their original position, including cases of embolization to the heart and lungs, causing serious and life-threatening problems which may result in a patient's death.[Nicholson (2010), An (2014), Kuo (2007), Mehanni (2016), Desjardins (2010), Vossen (2012), Pierichetti (2016), Sneed (2006), Vergara (2007), Duffie Video] These life-threatening and fatal complications were often asymptomatic before they became highly and suddenly symptomatic. On further questioning in his deposition, Dr. Asch added (pages 124-125):

124:22 Q. You -- in a clinical study,
124:23 sometimes you are able to avoid some of those events
124:24 because you're closely monitoring patients, correct?
125:1 A. Well, you're not avoiding the
125:2 events, the migrations or the fractures, but you're
125:3 identifying these asymptomatic events, which is key,
125:4 identifying them before they become lethal events.

COMPARISON TO PERMANENT FILTERS

22. The two permanent filters cited by Bard as predicate devices in the 510(K) application for the Recovery Filter, the Greenfield Titanium Filter (GF) and the Simon Nitinol Filter (SNF) have well-documented clinical records. Greenfield (1994), Greenfield (2000), Simon (1989), Bard SNF Brochure (2012) As cited predicate devices, these permanent filters form an appropriate basis from which to compare the performance of the Bard retrievable filters. In a comparison of filter types and relative rates of complications, Deso (2016) shows a migration rate for the Recovery and G2 filters at double and five times the rate respectively by comparison to the SNF. Deso (2016) Deso (2016) also show a fracture rate of Bard Recovery and G2 filters at more than ten times the rate of the Greenfield Titanium Filter. Deso (2016) A Bard Peripheral Vascular Safety Analysis from June 28, 2011, revealed that the Recovery filter had a reported fracture rate 55 times higher than the SNF. BPVEFilter-01-01824432

23. A 2014 study by Desai reported: "Patients with indwelling retrievable filters had significantly more complications than those with permanent filters (9% v. 3%; P .0001) after mean follow-up of 20 months." Desai (2014) "...Propensity score analysis demonstrated that even in the matched groups, indwelling retrievable filters were associated with significantly more complications than permanent filters (9.1% v. 3.5%; P=.0035)." Desai (2014) The authors concluded: "...device-related complications were more common with retrievable filters. Long-term use of retrievable filters should be avoided, especially considering the younger population in whom they are placed." Desai (2014)

24. A recent study by four Bard consultants reported the results of a retrospective review of 606 filter patients (240 permanent and 366 retrievable). The authors stated: "Device-related complications were more common in patients with retrievable filters (4.0% v. 0.4%)," a ten-fold higher complication rate. Consistent with other studies, the authors found that only 13.1% of the retrievable filters had actually been removed. Parker (2016)

CONCLUSION -COMPLICATION RATES ARE HIGH

25. Evidence cited earlier in this document has established that the weight of the evidence shows a significant rate of failure of the Bard Recovery and G2 filters after long-term implantation as measured by the incidence of IVC filter perforation and penetration of the vena cava walls sometimes into adjacent structures and organs, migration from the

original implantation site, and filter and filter element fracture and embolization. While the exact magnitude of the specific risks of a variety of complications may be debated, elevated long-term cumulative risk of all complications associated with these retrievable filters has become clear. Canadian Interventional Radiologist, Dr. Murray Asch, an acknowledged expert on IVC filters, who was selected by Bard to study its Recovery filter, stated in a May 2013 declaration to the Superior Court of the State of California, "There is an unacceptably and dangerously high rate of complications which lead to injury and death that have been identified with the Recovery® filter that is not present in other filters that I have used in my practice. These complications have also been observed in the medical literature concerning the successor devices to the Recovery® filter (G2® and G2 Express®). As an implanting physician I feel it is my responsibility to be sure my patients are safe. Consequently, it was important to me to identify patients who had the Recovery® filter implanted in their bodies so that appropriate medical monitoring of the patients could be provided to avoid adverse events and complications which were proven to lead to injuries and death."

RETRIEVABLE IVC FILTERS: PRESENT DAY CLINICAL CARE

26. In current day clinical medical practice, the norm is an absence of ongoing filter-related care for patients with IVC filters. Cumulative evidence shows that only a small percentage of retrievable filters are being removed, with rates as low as 3%, 8% and 13% in three recent series.[Gaspard (2009), Sarosiek (2016), Mohla (2016)] Analysis of 2008 Medicare data showed a low 1.2 to 5.1% annual retrieval rate.[Duszak (2011)] Tao (2016) states: "An issue that has emerged as a major health concern is the frequent lack of follow-up and failure to remove retrievable IVC filters."[Tao (2016)]

27 

[redacted]

THE PUBLISHED MEDICAL LITERATURE, EXPERTS IN THE FIELD, AND GOVERNMENT AGENCIES RECOMMEND MEDICAL MONITORING OF PATIENTS WITH RETRIEVABLE IVC FILTERS

28. Medical journal articles have noted this absence of ongoing monitoring for patients with retrievable IVC filters and have recommended initiation of a system to evaluate patients with implanted filters and to provide ongoing medical monitoring. Hull (2009), Nicholson (2010), Desai (2014), Tao (2016) Dr. William Nicholson, a cardiologist and coauthor of a paper published in the peer reviewed journal, *Archives of Internal Medicine*, stated, "It is essential that other medical centers evaluate patients who have received a Bard retrievable filter or any other IVC filter, both for patient safety and to corroborate our single-center findings."[4] Hull, an interventional radiologist, and Robertson, an engineer with Nitinol Devices and Components, co-authored a study of patients with Bard filters, reporting high complication rates, leading to the recommendation for the initiation of a medical monitoring system: "We are recommending imaging with abdominal CT to screen for perforation, fracture, and migration in patients with a Recovery filter in place." Hull (2009) A study from researchers at Stanford University noted the rationale for monitoring: "[F]ilter-related complications may go…unrecognized or underappreciated as potential causes of morbidity in patients …[This] supports the need that the filters must be monitored." Deso (2016) Authors of the Desai (2014) article state that "*systematic follow-up of patients with retrievable filters is necessary* to improve current retrieval rates." Desai (2014) As noted above, Dr. Asch recommended medical monitoring, as did Bard's July 2004 HHE. The medical monitoring protocol defined in this report provides a systematic follow-up of patients as called for by these and other experts who have published their opinions in the peer reviewed medical literature.

29. The American College of Radiology - Society of Interventional Radiology – Society for Pediatric Radiology, published a combined consensus statement in 2016 with revised Practice Parameters for the performance of IVC Filter placement. ACR-SIR (2016) In this expert consensus document, due to concerns regarding long-term safety, this societal consensus states, "When a retrievable filter is placed, the patient should be clinically reassessed periodically to weigh the benefits of continued filtration (need for PE prophylaxis) against the associated risks (*e.g.*, recurrent deep venous thrombosis [DVT], IVC thrombosis, symptomatic penetration, or mechanical failure) and uncertainties (given limited data on long-term mechanical stability and integrity of some devices)."ACR-SIR (2016) The Canadian Interventional Radiology Association (CIRA) in September of 2016 published their expert consensus position in favor of monitoring, "CIRA also reminds health care institutions of their responsibility to support registries or systems that

will help ensure patients receiving temporary IVC filters are appropriately monitored and notified of the need for removal contingent on the clinical circumstances and welcomes collaboration to ensure the safety of our patients." CIRA (2016)

30. The Government of Canada issued a National Alert (July 2016) addressing their concern about the risk of serious complications from IVC filters. Health Canada Alert (2016) In this National Alert to treating physicians, they stated their position regarding long-term follow-up, "Health Canada encourages physicians to participate in clinical studies or develop plans for long-term follow-up of the patients implanted with IVC filters so that data can be collected on the safety and effectiveness of IVC filters." Health Canada Alert (2016)

31. The United States Food and Drug Administration (FDA), as a result of safety concerns about retrievable IVC filters and long-term implantation, in their May 2014 Alert Update, invoked a requirement for ongoing clinical data collection of all device manufacturers. FDA Update (2014) This was required in one of two mechanisms: 1) participation in the prospective PRESERVE clinical trial or 2) post-market surveillance. Bard is enrolling patients into PRESERVE with only their Denali IVC filter design, and thus is not monitoring the patients who received Bard IVC Recovery and G2 filters (or the Bard Eclipse and Meridian filters). Bard is not listed on the FDA website's 522 listed studies as actively conducting post-market surveillance of patients with earlier generation filters, such as the Bard Recovery or Bard G2 retrievable IVC filters (or the Bard Eclipse and Meridian filters).

32. Ongoing full clinical data collection and medical monitoring such as that indicated and recommended in this document and the peer reviewed literature and medical society statements has not occurred and is not occurring for this group of patients with early generation retrievable Bard IVC filters (Bard Recovery and Bard G2). The existing practice of investigating adverse event reports pertaining to Bard filters may provide insight into factors contributing to these reported adverse events, but does not provide the medically necessary monitoring of patients with filters in place who have not already reported an adverse event. Bard documents acknowledge that the majority of patients with implanted retrievable filters are not followed or monitored by their physicians, organized programs or protocols (BPVE-01-00545320 – Sept. 2010).

PROPOSED MONITORING FOR BARD ECLIPSE AND MERIDIAN IVC FILTERS

33. The 2010 and 2014 FDA Alerts on IVC filter failures highlight concerns about all retrievable-type filters. The Bard Eclipse Filter, released in 2010, incorporated small design and manufacturing changes to the G2 Express platform. The primary change was electropolishing of the metal. [redacted] Biostatistician Rebecca Betensky updated a prior statistical analysis to include clinical data on Bard filters through Dec 2014. Betensky Bard Analysis (2017), Betensky Bard Report (2017) Betensky concluded that based on data through 2014 Eclipse IVC filters have a 5.8 times elevated risk of

fracture compared to SNFs. Structural engineering review of mechanical changes in the later generation (Eclipse and Meridian) filters by Mechanical Engineering Professor Robert McMeeking, PhD concludes that the changes from electropolishing have a minor clinical effect on protection from late filter fracture, "Therefore, I expect the only change due to the electropolishing of the limbs of the Eclipse to be a marginal improvement in the incidence of fracture due to fatigue when compared with the G2 filter family." As noted above, Bard's Filter – Fracture Analysis confirms that fracture of the Eclipse filter occurs, and was still taking place in 2016 at a level of increased risk that was only marginally better than the prior generation devices, which is, as I explain above, confirmation of my opinions regarding the effect of the design changes." McMeeking (2017) The Meridian Filter, introduced in August 2011, was predicated on the Eclipse Filter and added downward facing titanium leg anchors to decrease caudally-directed movement. Betensky's updated data review demonstrates an elevated 11.5 times rate of filter fracture as compared to SNF's. Betensky Bard Analysis (2017), Betensky Bard Report (2017) McMeeking agrees that the redesign elements of the Meridian Filter do not address, and therefore do not impact, many of the causes of adverse filter-related events, "I have demonstrated that tilt, perforation, endothelialization and fracture in the Meridian filter are no better than those of the Eclipse model. Fracture is only marginally improved over the G2 family and the other failure modes, other than perhaps caudal migration are unchanged." McMeeking (2017) Andreoli (2014) analyzed adverse event reporting to the FDA's MAUDE database from 2009-2012. In this study, Bard retrievable filters were treated as a group, clustering the Recovery, G2, G2X, G2 Express, Eclipse, and Meridian IVC filter. The data below is reproduced from Andreoli (2014) – Table 3.

	Bard Retrievable*
All complications	1,063
Fracture	288 (27.1%)
Migration	120 (11.3%)
Limb embolization	131 (12.3%)
Tilt	165 (15.5%)
IVC penetration	161 (15.1%)
VTE/PE	15 (1.4%)
IVC thrombus	21 (1.9%)
Placement issues	144 (13.5%)
Other	18 (1.7%)

Given the substantial evidence presented in this document that the complications of retrievable filters are time-dependent and cumulative, there is significant concern that the true incidence of complications from the newer Bard Eclipse and Meridian filters have not yet been fully recognized. Inclusion of the Eclipse and Meridian filters into the proposed monitoring protocol is highly recommended to respond to the increased risk associated with these devices with the same health benefits s as monitoring of the earlier generation Bard filters.

RECOMMENDED MEDICAL MONITORING PROGRAM FOR PATIENTS WITH BARD RECOVERY,G2, ECLIPSE, AND MERIDIAN IVC FILTERS

MONITORING PROGRAM GOALS

34. A Medical Monitoring Program is prudent, necessary and reasonable, for the important reasons detailed herein. It has been established with the weight of the evidence that patients who have undergone implantation of Bard Recovery and G2 IVC filters and have not had their filter removed remain at substantially increased risk to suffer serious complications. As such, these patients will be designated herein as having at-risk IVC filters. A Medical Monitoring Program is recommended to identify surviving patients who have had one of these filters implanted and not retrieved to date. Imaging is recommended to evaluate the present condition of that at-risk filter. A Medical Monitoring Program will accomplish several critical health benefits : 1) the monitoring program will identify patients who retain at-risk filters, thereby creating an alert to the patient and his/her treating physicians about issues related to this potentially hazardous device. 2) The program will provide important and clinically helpful diagnostic information, which at present is lacking, regarding the presence of filter complications through an imaging protocol (described in subsequent paragraph). Findings detected by this monitoring in many cases are likely to identify a situation or factor, previously unknown, which marks a substantially increased risk of future complications. 3) By providing this medical data, which is currently not routinely obtained on at-risk patients, crucial diagnostic information will become available to patients and their treating physicians, leading to an accurate understanding of the current filter condition and, as a result of that knowledge, facilitate steps towards the prevention and/or mitigation of severe, life-threatening and fatal complications.

TIMING OF INITIATION OF MONITORING

35. The vast majority of patients, if not all, with Bard Recovery and Bard G2 filters have had the retrievable filter in their bodies well in excess of the minimum 90 day time period (meaning the time interval between implantation of the filter and initiation of the monitoring) recommended herein. (Most have had the filter implanted and not yet retrieved for a period of years.) Therefore it is safe to say that ALL patients with a Bard Recovery, G2, Eclipse or Meridian filter are recommended for monitoring. A 2014 updated FDA Alert concerning retrievable IVC filters recommended strong consideration of retrievable filter removal as soon as protection from PE is no longer needed. FDA Update (2014) The FDA Alert contained a mathematical decision analysis examining the optimal timing for filter retrieval. Morales (2013) "The mathematical model suggested that if the patient's transient risk for pulmonary embolism has passed, the risk/benefit profile begins to favor removal of the IVC filter between 29 and 54 days after implantation." FDA Alert (2014) The proposed Medical Monitoring Protocol utilizes 90 days post implantation as the date to begin monitoring. If one examines the risk curve presented in the Morales

mathematical analysis (figure 4), there is a calculated theoretical protective effect of the retrievable filter, which begins to gradually abate beyond day 54. The authors analyze this with a statistic of net risk score, summing the positive and negative outcomes into a cumulative assessment. The protective effect is at its maximum between 5 and 8 weeks after filter placement.[Morales (2014)] And, while the degree of beneficial filter effect gradually diminishes, the filter still provides a net protective effect in the period beyond 8 weeks. By extending the initiation period to begin monitoring to at least 90 days post-implant, a minimal additional cumulative reduction in protective benefit is encountered. This 3-month period to remove a retrievable filter gives adequate time for the at-risk population to recover from the original high-risk situation which prompted filter placement and provides a practical yet safe interval to arrange elective removal.

36. Evidence shows that the majority of patients with Bard retrievable IVC filters have retained their filter well beyond 90 days post implantation, as previously stated, with published reports showing that a minority of potentially retrievable filters have been removed.[Gaspard (2009), Sarosiek (2016), Mohla (2016), Duszak (2011)] As these filters have been implanted since 2003, at present day many surviving patients will have gone for long periods post-implantation without removal or follow-up evaluation. Bard's promotional literature shows the Recovery filter was available in 2003 and manufacturing of new units was stopped upon the release of the Bard G2 filter in September of 2005. The Bard G2 became available in 2005 and was modified as other G2 sub-types (G2 Express and G2x) in 2008. These filters were ultimately replaced in the product line by the Bard Eclipse filter, introduced in 2010. Subsequently, Bard has produced the Meridian and Denali IVC filters. Bard internal sales data show sales of the Recovery filter from 2003 through 2008, so that even though these filters were no longer being manufactured, they were still being sold for several additional years. Bard Quarterly Sales Data show a cumulative total of approximately 32,000 Bard Recovery filters were sold between 2003 and 2008.[BPV-17-01-00193291] It is important to recognize that these devices have extended shelf lives, so that Bard Recovery filters sold in 2008 may have been implanted up to several years after that time.

MEDICAL MONITORING IMAGING RECOMMENDATIONS:
NON-CONTRAST CT SCAN

37. The proposed Medical Monitoring Protocol recommends that upon entry into the protocol imaging of the filter and surrounding structures be performed with a non-contrast CT scan of the abdomen. The high quality cross-sectional imaging obtained from this CT scan is planned as a one-time testing to investigate the current state of the at-risk filter and guide clinicians to the best care options available from that point. While different forms of imaging are potentially available, and I have considered the pros and cons of each of them for purposes of this report, CT scanning of the abdomen showing the IVC and surrounding structures is the best choice and is recommended to accomplish several benefits of the monitoring. This non-contrast CT scan provides an excellent cross-sectional evaluation of the filter and surrounding structures.[Miller (1986)] Most importantly, this CT imaging is highly accurate in determining the presence or absence of complications. Imaging experts have published clear recommendations favoring CT

imaging on this issue: "We are recommending imaging with abdominal CT to screen for perforation, fracture and migration in patients with a Recovery filter in place." Hull (2009) Information from this monitoring imaging study provides a detailed and accurate assessment of the current status of the device and provides critical information as to the safety and difficulty of possible filter removal. This information is, therefore, a critical element needed to assist in the decision for a potential filter retrieval attempt. Experts from the University of Pennsylvania explain why this CT imaging is critically important to obtain *prior* to a retrieval attempt, "a priori knowledge of a potentially complicated retrieval is beneficial, because it can aid in procedure planning, proper patient consent, guiding of patient expectations, and a potential referral to a center that specializes in complicated filter retrieval." Dinglasan (2012)

38. To further understand the importance of this monitoring evaluation, one must recognize that ultimately, not all patients after consideration of all factors will be recommended for a percutaneous filter retrieval attempt. As summarized in the FDA alerts, filter retrieval is a clinical decision based on an assessment of the risk and benefit of the filter. Some patients will remain at increased risk for pulmonary embolism and will require ongoing IVC filtration. Others will continue to harbor a contraindication to anticoagulant therapy. Others will have advancement of underlying severe medical conditions (metastatic cancer, advanced heart failure, etc.) where the potential risks of the procedure to retrieve the filter cannot be justified. If the filter is found to be fractured or malpositioned by this monitoring CT scan, an increased complexity and risk may be present at the retrieval procedure and special preparations and additional equipment may need to be arranged before attempted percutaneous retrieval. Open surgical retrieval of the IVC filter may be recommended in specific situations. The information from the proposed monitoring CT scan will yield important diagnostic information not available otherwise, providing the most complete data to patients and their treating doctors to facilitate this assessment and guide them towards the best outcomes. No matter what clinical decisions are ultimately made about the retrieval after the monitoring, the benefit of obtaining timely diagnostic information exists for all members of the population at risk. All face an increased risk due to the filters, and all will benefit from the monitoring in the form of a CT Scan if it is made available and they choose to have it done.

VENOGRAPHY/FILTER RETRIEVAL IS A TREATMENT MODALITY, NOT AN EVALUATION TOOL

39. Contrast venography is not being recommended as part of this monitoring protocol. Performance of venography as a stand-alone diagnostic procedure has commonly been replaced by imaging of veins with noninvasive techniques (Color-flow Duplex Ultrasound and CT venography). If the clinical decision is made to proceed with a filter retrieval attempt, current IVC filter retrieval practices include IVC contrast venography performed at the outset of the removal/retrieval procedure. The venography that accompanies a retrieval attempt is invasive in nature and requires administration of intravenous contrast with potential complications of kidney dysfunction and allergic reaction. Information from this venography, which shows the blood flow and internal aspects of the IVC, is supplemental to the information obtained from the pre-procedure

CT scan and is not equivalent or redundant to the information provided by the CT scan.

40. Procedures to remove retrievable IVC filters, like all invasive procedures, are not without intrinsic risks. While the safety record of published series of retrieval procedures is adequate, complications are encountered in a small percentage of patients. Binkert (2009) Recent articles detail complex and advanced techniques at specialty centers to achieve safe retrieval in the highest percentage of patients. Oh (2001), Dinglassen (2013), Iliescu(2012) Shah describes a 2.3x rise in the risk of complex retrieval after 180 days. Shah (2016) It is important to note that filter removal by open surgical techniques has been performed and is recommended in some situations. Stein (2004), Shang (2011), Connelly (2012), Malgor (2012) This may be necessary after unsuccessful attempts at percutaneous retrieval, due to filter penetration into an adjacent organ, or for other specific reasons (i.e. extreme tilt or migration into the renal vein) at the discretion of the specialist. Information to determine the need for open removal is accurately obtained by the recommended CT scan, and would not be adequately delineated by venography alone. Fundamentally, contrast venography is a supplement to the retrieval process and does not meet the requirements of a beneficial medical monitoring intervention.

CLINICAL BENEFITS OF MONITORING PROGRAM

41. The clinical benefits of this Medical Monitoring Protocol to patients and their treating doctors are to accurately diagnosis the current status of the filter, to aid the assessment of whether removal is warranted to inform the removal process, and to provide a systematic identification and notification of patients with at-risk filters. The majority of these patients, and often their treating physicians, are unaware of the potentially dangerous situation that exists with their Bard retrievable IVC filter as it is documented in the literature and the FDA data. Upon entering the Monitoring Protocol these patients will obtain a CT Scan of the abdomen yielding highly sensitive and accurate diagnostic information about the current status of their filter and the presence of any current complications. Armed with this diagnostic information, these patients and their treating doctors and then determine if it is appropriate to consult the interventionalist who placed the filter or another specialist and seek consultation regarding the risks and benefits of removal of their at-risk Bard retrievable IVC filter. Detailed information from this monitoring will assist in the critical clinical decision regarding attempting filter removal, and, if so, whether that retrieval should be attempted percutaneously or through an open approach. Without this monitoring information, the patient and treating physicians cannot make a fully intelligent and informed decision regarding the best way to proceed with their at-risk filter. It is important to understand that a filter retrieval attempt will not be a universal recommendation to this patient group and not all patients, after hearing the risks, benefits and alternatives, will elect to undergo the retrieval procedure. Patients and their doctors will obtain important benefits from obtaining the highest quality diagnostic information to guide decision-making in this challenging situation.

PERSPECTIVE OF A CLINICAL PHYSICIAN

42. Notwithstanding the extensive citations of the medical literature in this report, I can also share my experience, knowledge and perspective as a clinical vascular specialist who cares for patients with IVC filters. Even after the FDA alerts, medical articles and recommendations from medical societies and governmental agencies regarding increased complications associated with retrievable IVC filters, no system-based organized programs to alert patients and their doctors are in place at my medical center, hospital system or other area hospitals to my knowledge. In my experience, the average patient does not know what type of filter has been implanted, whether it is a retrievable-type filter, and, if so, whether retrieval is planned and how that will be accomplished. After discharge from the hospital, the average patient's primary care physician, who may not have attended to them while they were hospitalized in typical practice, is not alerted to the presence of a retrievable IVC filter in their patient and, therefore, is not likely to address any concerns related to its presence or perform follow-up imaging. This personal experience is consistent with the medical literature cited in this report. I, therefore, see great potential benefit in and need for a Monitoring Program such as the one outlined in this document.

MEDICAL MONITORING IS AN ACCEPTED PUBLIC HEALTH INTERVENTION AND IS CONSISTENT WITH THE INTEGRITY OF INDIVIDUALIZED PATIENT FOLLOW-UP CARE

43. Medical monitoring and screening programs are well-recognized public health tools used in situations where the monitoring will lead to substantial benefits to individuals in a defined population of patients. These benefits include early diagnosis, prevention, and mitigation of disease or injury to a population at risk, given that it is based on an assessment that the benefits exceed the risk of monitoring. A monitoring program should be based on utilizing the least invasive method that will yield the most clinically meaningful information.

44. Medical monitoring and screening programs are a population-based tool for a population sharing a common risk factor (*i.e.*, age for colon cancer screening with colonoscopy and for breast cancer screening with mammography in women). The utility of the monitoring does not depend on uniformity of individualized patient characteristics, rather it focuses on one or more significant common risk factors that renders the monitoring medically necessary and prudent, even though there are numerous differences among the patients in the population to be monitored.

45. Monitoring and screening is indicated based on the risk concern at issue (such as colon cancer, breast cancer, or IVC filter complications), and it is routinely and appropriately done in response to a single dominant risk factor to define what population should receive the monitoring. These recommendations apply to the defined populations regardless of the presence or absence of other risk factors and patient characteristics. In other words, if the patient has the risk factor or factors of interest (here, for example, the implanted at-risk IVC removable filter in place for greater than 90 days), it is recommended he/she

should be monitored regardless of the presence or absence of other risk factors or common individualized medical history characteristics. Providing such monitoring in the form of diagnostic and preventive information to members of an at-risk population and their treating doctors is viewed by the medical profession including clinicians as entirely consistent with appropriate medical care and with individualized patient care. The use of medical monitoring and screening programs as a public health tool is not understood by the medical profession or public health experts to interfere with the doctor - patient relationships of the persons being monitored. Rather, the monitoring provides useful diagnostic information to the treating doctor to ultimately enhance his or her care of the patient. This is especially true because medical monitoring programs, including the one recommended here, are voluntary, not mandatory, and a patient with guidance from his or her treating physician, if desired, can decide whether to participate or not, as they deem proper.

CONCLUSIONS

46. In conclusion, careful review of the totality of the evidence demonstrates that the population of patients with a Bard Recovery, G2, Eclipse and Meridian filters who have not had their filters removed are at increased risk of experiencing serious complications. These patients and their treating doctors are in need of specialized diagnostic information to diagnose, prevent and or mitigate serious complications resulting from this implanted medical device. This document has established that sufficient risk is present to warrant medical monitoring in this at-risk patient group. A Medical Monitoring Program for this population that shares the common risk of a Bard Recovery, G2, Eclipse and Meridian IVC filters that have not been removed after 90 days post-implantation is recommended as an essential tool to provide for the best care of this patient group. Such monitoring is recommended by numerous experts in the field and published in the peer-reviewed literature, by national and international medical societies and by national governmental health departments of the United States and Canada. There exists a well-accepted, safe and beneficial noninvasive diagnostic medical procedure in the form of an abdominal CT Scan that can provide critical information that is not otherwise available and is likely to lead to the prevention and/or mitigation of serious filter-related complications. This type of monitoring is prudent and medically necessary; however is not presently being done in clinical practice. As summarized in the information presented in this report, this Medical Monitoring Program will: 1) identify the patients who remain at-risk for filter-related complications, 2) provide for the most accurate noninvasive diagnosis of filter-related complications, and 3) give essential information and meaningful assistance in prevention and/or mitigation of progression to more serious or life-threatening complications.

I hold all of my opinions to a reasonable degree of medical certainty. If I receive additional pertinent information, I reserve the right to supplement this report.

Steven M. Hertz, M.D. 2/3/2017

Steven M. Hertz, M.D. Date:

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REVIEWS

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PRESENTATIONS

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Hertz SM. Magnetic Resonance Angiography: Clinical Utility. Noninvasive Vascular Laboratory: Principles and Practice. 9/19/97. Parsippany, NJ

Hertz SM. Compression Treatment of Arterial Pseudoaneurysms. Noninvasive Vascular Laboratory: Principles and Practice. 9/25/98. Whippany, NJ

Hertz SM. Management of Central Vein Stenosis. Venous Disease and Vascular Interventions. 3/6/99. Short Hills, NJ

Hertz SM. Thrombin Injection of Pseudoaneurysms: Avoiding Complications. 5/3/01. Eastern Vascular Society Annual Meeting. Washington, DC.

Hertz SM. Stroke-Signs, Symptoms and Treatments. 4/8/02. St Barnabas Senior Health Group. St. Barnabas Medical Center, Livingston, NJ.

Hertz SM. Vascular Laboratory Accreditation. 5/5/02. Vascular Society Annual Meeting. Boston, MA.

Hertz SM. Lower Extremity Bypass Graft Surveillance. 12/7/02. American College of Surgeons, New Jersey Chapter 51st Annual Meeting. Princeton, NJ

Hertz SM. Renal Artery Stenosis: Imaging. Symposium on Renal Artery Stenosis. 6/4/03. Saint Barnabas Medical Center. Livingston, NJ

Hertz SM. Vascular Laboratory: Current Trends. Medical Grand Rounds. 9/11/03. Newark Beth Israel Medical Center. Newark, NJ

Hertz SM. Aortic Endografts: Preoperative Evaluation. Noninvasive Vascular Laboratory: Principles and Practice. 9/12/03. Morristown, NJ

Sulliman, Y, et al. Does Suprarenal Fixation Without Barbs Prevent Migration? Presented at the 26th Annual Meeting of the Vascular Society of New Jersey, 3/16/05, Summit, NJ.

Hertz SM. Arterial Noninvasive Testing. Presented at the Annual Meeting of the Society For Vascular Ultrasound, North Jersey Vascular Association, 4/16/05, Morristown, NJ.

Moderator, Hemodialysis Access Session, 5th Noninvasive Vascular Laboratory Symposium, 10/6/06, Morristown, NJ.

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Anesthesia and Carotid Artery Procedures. Grand Rounds Department of Anesthesia. 11/18/09. St Barnabas Medical Center, Livingston, NJ.

Vascular Evaluation and Treatment in Wound Care Patients. Wound Care Center. 05/24/10. St. Barnabas Medical Center, Livingston, NJ.

Aortic Aneurysm Repair-An Update. Grand Rounds Department of Anesthesia. 9/8/10. St. Barnabas Medical Center, Livingston, NJ.

What's New in Vascular Surgery. Grand Rounds Department of Medicine. 4/29/11. Bayonne Medical Center, Bayonne, NJ.

PVR Interpretation. Society for Vascular Ultrasound-NJ Vascular Association. 10/29/11. Morristown Memorial Hospital. Morristown, NJ.

Transcranial Doppler: Early Experience. N. Jersey Chapter – Society For Vascular Ultrasound. 5/2/15. Hackensack Medical Center, Hackensack, NJ.

Transcranial Doppler: Alternate TCD Parameters to Detect Cerebral Vasospasm. Advanced Vascular Imaging and Diagnosis. 11/21/15. New York, NY.

Amputation After-Care: Role of the Vascular Surgeon. Amputee Support Group. 9/13/16. Kessler Institute of Rehabilitation, West Orange, NJ.

Current Research Protocols:

Transcranial Doppler. Principal investigator. Institutional IRB-approved.
St Barnabas IRB Study Number 15-26
"Analysis of Initial Experience with Transcranial Doppler to Predict and Identify Cerebral Vasospasm"

Hertz – Exhibit B

List of Depositions and Court Testimony
STEVEN M. HERTZ, MD 2013-2016

10/28/2013.
DEPOSITION-Defense medical expert.
(Malpractice)
Littig v Scotti

10/24/2016.
DEPOSITION-Plaintiff medical expert.
(Liability)
Williams-Stevens v Newark Public Schools